

REMARKS

The Final Office Action dated May 4, 2010 has been received and reviewed. Claims 1 to 22 and 48 to 66 are pending in the application.

Claims 1-3, 6-22 and 48-51 are rejected.

Claim 1 has been amended. Support for the amendment can be found for example on page 26, line 18 to page 27, line 3; and Figures 3, 4A-4F, and 5-8.

Claim 52 is objected to. Applicants thank the Examiner for indicating the allowability of claim 52 if rewritten in independent form.

35 U.S.C. §103 Rejections

Claims 1-3, 6-8, and 12-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270). Applicants respectfully disagree.

In support of the obviousness rejection of claims 1-3, 6-8, and 12-17 over Warthoe et al. in view of Buechler, it is asserted that Buechler teaches a flow front control feature in the form of "fluid control means 18" and that one of ordinary skill in the art would be motivated to include the fluid control means of Buechler in the apparatus of Warthoe et al. *Office Action*, pages 9-10 (October 22, 2009). As previously argued, Applicants respectfully submit that the "fluid control means 18" of Buechler et al. is not, however, described as controlling progression of a leading edge of a bolus of material moving across the diagnostic element 6. Rather, the fluid control means 18 is described as functioning to slow the rate of fluid flow over the diagnostic element 6 after the fluid has already passed over the surface of the diagnostic element 6. See, e.g., Buechler, column 15, lines 4-12 and lines 24-29; column 22, lines 29-45. In other words, the fluid control means 18 cannot control the progression of the leading edge of the fluid over the diagnostic element 6 because the fluid has already passed over the surface of the diagnostic element 6.

In the interest of advancing prosecution however, Applicants have amended claim 1 to specify that the flow front control feature(s), are located only on the opposing surface, e.g., not on the detection surface. Buechler fails to teach or suggest that the flow front control features are located only the opposing surface. Rather, Buechler teaches that the flow front control features is located on detection surface 6,

while the opposing surface is typically smooth. See, e.g., col.18, lines 22-25. Any discussion of a flow front control feature on the opposing surface in Buechler is taught only in conjunction with flow front control features on the detection surface.. See col. 18, lines 25-30.

‘ In addition, claim 3 recites that "the flow front control feature comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber." The only "fluid control means 18" disclosed or suggested by Buechler is a gap or slot formed between elements 8 and 9 in, e.g., Figure 1D of Buechler. Contrary to the assertion made in the Office Action, Buechler does not teach "that the flow control means can comprise discrete structures protruding from and separated by a land area on the opposing surface of the diagnostic element." *Office Action*, page 10 (October 22, 2009). Applicants respectfully submit that this shortcoming provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claim 3.

In addition to the reasons presented above with respect to all of claims 1-3, 6-8, and 12-17, claim 16 recites a sealed module attached to the housing containing the detection chamber, where the sealed module itself contains "a first chamber comprising a liquid located therein; a second chamber comprising a selected reagent located therein; and an inter-chamber seal isolating the second chamber from the first chamber within the at least one module." Applicants note that none of the cited portions of Warthoe et al. teach or suggest this combination of features in one sealed module (nor does Buechler address these features either). Applicants respectfully submit that this shortcoming provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claim 16.

For at least the reasons presented above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 1-3, 6-8, and 12-17 over Warthoe et al. in view of Buechler. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claim 9 and 48-50 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claims 1 and 8 above, and further in view of Hodges et al. (US

2003/0180814). Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Beebe et al. (US 2003/0077836). Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Ohman et al. (US 2005/0042766). Claims 18, 19, 22, and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Tisone (US 2006/0292304). Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270) and Tisone US 2006/0292304), as applied to claims 18 and 19 above, and further in view of Beebe et al. (US 2003/0077836). Applicants respectfully disagree with the above rejections and the assertions made in support of it.

Claims 9-11, 18-19, 20-22, and 48-51 depend directly or indirectly from claim 1. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claim 1. Applicants further note the addition of Hodges, Beebe, Ohman, or Tisone, either alone or in combination, do not address the deficiencies in the *prima facie* case of obviousness.

In addition, Applicants submit that, despite assertions to the contrary, Tisone does not teach or suggest "an exit seal closing the exit port" of a module, nor does Tisone teach or suggest that "movement of the plunger towards the exit port opens the exit seal." Although a variety of paragraphs and figures from Tisone are cited in support of this obviousness rejection, a careful review of the cited portions reveals no exit seal or opening of the exit seal by advancement of a plunger. For at least that reason, Applicants respectfully submit that the combination of Tisone with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claims 18-21.

Reconsideration and withdrawal of the obviousness rejections as discussed above are, therefore, respectfully requested.

Conclusion

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 733-2180. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,

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